UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

EBONIA ELLIOTT-LEWIS, et al.,	*	
	*	
Plaintiffs/Relators,	*	
	*	
v.	*	Civil Action No. 14-cv-13155-IT
	*	
ABBOTT LABORATORIES, INC.,	*	
	*	
Defendant.	*	

MEMORANDUM & ORDER

March 28, 2016

TALWANI, D.J.

I. Introduction

This qui tam action alleges that Abbott-Laboratories, Inc. ("Abbott" or "Defendant") violated the False Claims Act, 31 U.S.C. § 3729, and the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b. Plaintiff/Relator Ebonia Elliott-Lewis ("Elliott-Lewis"), a former Abbott employee, also claims that Abbott unlawfully retaliated against her in violation of 31 U.S.C. § 3730(h). Presently before the court is Defendant's Motion to Dismiss [#14].

II. Factual Background as Alleged in the Complaint

Elliott-Lewis was the Regional Medical Science Manager, Northeast, for Abbott from approximately June 2010 until May 9, 2014. Compl. [#1, ¶¶ 10, 71]. Elliott-Lewis claims that Abbott engaged in illegal, off-label promotion of its XIENCE V Stent (Everolimus Eluting Coronary Stent) ("XIENCE"), and illegal, pre-approval promotion of its ABSORB BVS (Bioresorbable Vascular Scaffold) ("ABSORB"). Compl. [#1, ¶¶ 13, 18(a), (b)].

According to Elliott-Lewis, XIENCE is a metal scaffold with the drug everolimus contained in a thin coating. Compl. [#1, ¶ 23]. The stent is mounted on a folded balloon and placed in the coronary artery. Compl. [#1, ¶ 23]. Elliott-Lewis claims that Abbott engaged in off-label promotion of XIENCE, specifically through tools like the Chief Medical Officer's U.S. Newsletter. Compl. [#1, ¶ 46].

ABSORB is a drug eluting, bioresorbable scaffold that is placed in the coronary artery. Compl. [#1, ¶ 24]. The device is described by Elliott-Lewis as innovative in that it naturally dissolves after implantation. Compl. [#1, ¶ 25]. ABSORB is an investigational device that is in the trial phase for FDA approval in the United States, but has yet to receive such approval. Compl. [#1, ¶ 32]. Elliott-Lewis claims that Abbott engaged in pre-approval promotion of this investigational device. Compl. [#1, ¶ 18(b)]. Specifically, Elliott-Lewis claims that Colleen Baird ("Baird"), her immediate supervisor, and Regina Deible ("Deible") gave inappropriate promotional presentations about ABSORB to a hospital group and at a continuing medical education conference. Compl. [#1, ¶¶ 39-41]. Elliott-Lewis claims that Deible presented slides showing the "best long-term outcomes" using "the Bioresorbable Vascular Scaffold" in the superficial femoral artery. Compl. [#1, ¶ 43]. Elliott-Lewis claims that ABSORB's clinical trial is limited to its use in the coronary artery. Compl. [#1, ¶ 55]. Elliott-Lewis claims that such promotion of an investigational device illegally primed the marketplace before the legal product introduction. [#1, ¶ 44].

Elliott-Lewis alleges that Abbott exerted pressure on her to reach out to clinical leaders in the Northeast region in an effort to influence those leaders to meet stent sales goals and claims that Abbott rewarded the off-label promotion as well as pre-approval promotion of the two devices. Compl. [#1, ¶ 28]. The complaint alleges a series of events where Elliott-Lewis' job

responsibilities were reduced after she refused to participate in the illegal marketing and promotion. She asserts that her supervisors retaliated against her by reducing her job responsibilities, hiring her replacement, excluding her from training and department activities, ignoring her requests for assistance with clinician-initiated requests, documenting unduly negative remarks about her job performance, suspending her pay, and terminating her employment. Compl. [#1, ¶11].

Specifically, Elliott-Lewis claims that between late 2012 and early 2013, Abbott's National Medical Science Manager and Regional Medical Science Manager for the Southeast Region, told her that Abbott's Office for Ethics and Compliance opposed the idea of the Medical Science Group giving presentations about ABSORB. Compl. [#1, ¶¶ 22, 32]. Elliott-Lewis informed Baird about the Office for Ethics and Compliance concerns, nevertheless, Baird made the presentation to a hospital group. Compl. [#1, ¶ 32]. Elliott-Lewis claims that several of her high profile projects were then reassigned to Baird throughout 2013. Compl. [#1, ¶32]. Elliott-Lewis claims that in mid-August 2013, Abbott hired Deible, and asked her to cover assignments in geographic areas that would normally fall within Elliott-Lewis' purview. Compl. [#1, ¶¶ 33, 29(2)].

Elliott-Lewis also alleges that management used her 2013 performance review to document unduly negative remarks to induce her resignation. Compl. [#1, ¶ 29(4)]. Elliott-Lewis claims that on February 12, 2014, she met Baird in Connecticut for a field ride and performance review. Compl. [#1, ¶ 34]. However, the performance review was postponed at the request of Baird because Baird said she needed to rewrite the review based on feedback from Chuck Simonton ("Simonton"), Abbott's Chief Medical Officer, and Krishna Sudhir ("Sudhir"), Vice President of Medical Affairs and Product Performance. Compl. [#1, ¶ 22, 34]. Realizing

that her managers (Baird, Simonton and Sudhir) were trying to compel her to comply with illegal marketing, or to damage her credibility, Elliott-Lewis opened an internal compliance complaint on February 13, 2014, accusing them of retaliation and harassment. Compl. [#1, ¶ 18]. At the direction of a human resources manager, Elliott-Lewis also opened a separate personnel ticket on February 20, 2014, by calling an intake hotline. Compl. [#1, ¶ 19]. Elliott-Lewis claims that during this time she was intentionally excluded and isolated from key team activities, such as a training and team meeting held in Santa Clara, CA. Compl. Compl. [#1, ¶ 35].

III. Standard

To survive a motion to dismiss, a complaint must include factual allegations that, taken as true, demonstrate a plausible claim for relief. Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 – 58 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). Evaluating the plausibility of a complaint is a two-step process. "First, 'the court must separate the complaint's factual allegations (which must be accepted as true) from its conclusory legal allegations (which need not be credited).' Second the court must determine whether the remaining facts allow it to 'draw the reasonable inference that the defendant is liable for the misconduct alleged.'" Jane Doe No. 1 v. Backpage.com, LLC, __ F.3d __, 2016 WL 963848, at *9 (1st Cir. March 14, 2016) (citations omitted); see also, Air Sunshine, Inc. v. Carl, 663 F.3d 27, 30 (1st Cir. 2011) (The court does "not accept the complaint's legal conclusions . . .") (internal quotation marks omitted).

IV. Analysis

a. Count I, False Claims Act, 31 U.S.C. § 3729

The False Claims Act is a statutory scheme created "to forestall fraud against the federal government, by proscribing the presentment of any 'false or fraudulent claim for payment or approval' to the United States." Harrington v. Aggregate Indus. Northeast Region, Inc., 668 F.3d 25, 30 (1st Cir. 2012) (internal citations omitted). The statute "attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the claim for payment." United States v. Rivera, 55 F.3d 703, 709 (1st Cir. 1995) (internal quotation marks omitted); see also United States ex rel. Ge v. Takeda Pharm. Co. Ltd, 737 F.3d 116, 124 (1st Cir. 2013) (merely alleging defendant's misconduct is not enough, complaint must establish that false claims were submitted to the government for payment).

Abbott argues that the allegations under the False Claims Act in Count I fail because Elliott-Lewis failed to plead the existence of a false or fraudulent claim for payment that was presented to the United States. Def.'s Mem. of Law in Supp. Mot. to Dismiss [#15, at 7, 11]. "Nowhere does she allege that anyone presented a false reimbursement claim for ABSORB or XIENCE to the government - let alone one caused by Abbott's allegedly improper marketing." Id. at 8. Defendant also argues that Elliott-Lewis merely speculates that two presentations by Abbott to a group of physicians "will cause false claims to be submitted to the government by unidentified doctors (whether or not they attended either of the presentations), at some undefined point years in the future, for unspecified procedures, if the product is ultimately approved in the United States." Def.'s Mem. of Law in Supp. Mot. to Dismiss [#15, at 12].

Elliott-Lewis counters that she did specify false claims that have already occurred. "In Paragraph 53 of the relator's complaint, she alleges false claims that have already occurred:

claims for Medicare reimbursements for ABSORB III clinical trials." Pl.'s Opp'n to Def.'s Mot. to Dismiss [#22, at 9-10]. Elliott-Lewis does not identify any particular claim or invoice submitted to the government. She argues that she is unable to plead with more particularity the precise nature of the claims because she does not have pre-discovery access to all the information. Id. at 10.

Elliott-Lewis' allegations are insufficient under the False Claims Act. Elliott-Lewis can point to no set of facts alleged in the complaint where a claim for reimbursement was submitted to the government. See United States ex rel. Ge, 737 F.3d at 124 ("Because FCA liability attaches only to false *claims*, merely alleging facts related to a defendant's alleged *misconduct* is not enough.") (emphasis original) (internal citation omitted). While Elliott-Lewis' claim that "[b]efore FDA approval, if a device maker describes uses that are not ultimately approved, that medical device company is creating an off-label promotion scenario that will inappropriately influence the healthcare marketplace when the legal commercial product introduction finally occurs," Compl. [#1 ¶ 44], this is not enough under the False Claims act. United States ex rel. Rost v. Pfizer, Inc., 507 F.3d 720, 727 (1st Cir. 2007) ("FCA liability does not attach to violations of federal law or regulations, such as marketing of drugs in violation of the FDCA, that are independent of any false claim.") (*abrogated on other grounds by* Allison Engine Co., Inc. v. United States ex rel. Sanders, 553 U.S. 662 (2008)).

Elliott-Lewis contends "that because the false claim is based on pre-approval promotion, every resulting post-approval BVS Medicare or Medicaid payment will be subject to penalties. Upon FDA approval, if Abbott successfully uses false claims and product seeding tactics to supplant half of its own metal stent sales with BVS device sales, the US government will pay at least $250 Million annually as a consequence." Compl. [#1, ¶ 56]. While Elliott-Lewis'

complaint may describe illegal practices in which Defendant allegedly engaged, those practices, even if illegal, "are not a sufficient basis for an FCA action because they do not involve claims for government reimbursement." United States ex rel. Rost, 507 F.3d at 732. Missing from Elliott-Lewis' complaint are allegations that as a result of the off label promotion, claims were submitted to the government. Elliott-Lewis has identified no specific entities who submitted claims, nor has she identified government program payers, or the times, amounts, or circumstances of such claims. United States ex rel. Karvelas v. Melrose-Wakefield, Hosp., 360 F.3d 220, 225 (1st Cir. 2004) ("[A]n actual false claim is the sine qua non of a False Claims Act violation.") (internal quotation marks omitted) (*abrogated on other grounds by* Allison Engine Co. v. United States ex rel. Sanders, 553 U.S. 662 (2008)). Devoid of allegations that there were claims for payment submitted to the government, Elliott-Lewis' claim under Count I is dismissed.

b. Count II, Anti-Kickback Statute, 42 U.S.C. § 1320a-7b

Abbott argues that Count II of the complaint must be dismissed because Elliott-Lewis failed to allege that Abbott provided any kickback to any healthcare provider and failed to allege that a claim for payment was made as a result of such inducement. Mem. in Supp. Mot. to Dismiss [#15, at 13-14]. Elliott-Lewis counters that "[b]y holding these special presentations and illegally promoting the use of ABSORB and XIENCE, Abbott induced certain groups of physicians and healthcare providers to gain access to highly-desirable and new technology." Opp'n to Def.'s Mot. to Dismiss [#22, at 16-17]. Count II states that "Abbott has engaged in conduct which violates Sunshine Laws and 42 U.S.C. § 1320a-7b (Anti Kick-back Statute) by engaging in conduct that improperly seeks special arrangements between Abbott and medical

providers in exchange for special or preferential treatment in violation of federal law." Compl. [#1, ¶ 69].

The Anti-Kickback statute makes it illegal to knowingly and willfully pay remuneration to induce a person to use or recommend any item or service for which payment may be made under a Federal health care program. 42 U.S.C. § 1320a-7b(b)(2). A False Claims Act claim based on a violation of the Anti-Kickback statute requires that kickbacks "affected the transaction underlying the claim." United States ex rel Hutcheson v. Blackstone Med., Inc., 647 F.3d 377, 394 (1st Cir. 2011). Compliance with Anti-Kickback statute is a precondition of Medicare and Medicaid payment, and liability has been found when a defendant falsely certified compliance with the Anti-Kickback statute.

Contrary to Elliott-Lewis' assertion, the complaint does not adequately allege a False Claims Act claim based on a violation of the Anti-Kickback statute. Again, the complaint fails to identify any false claims for payment, and it similarly fails to allege any kickbacks given to a medical provider. Elliott-Lewis' allegation that Abbott hosted presentations or gave educational grants to continuing medical education conferences is insufficient to state a claim for a False Claims Act claim based on a violation of the Anti-Kickback statute. See, New York v. Amgen, Inc., 652 F.3d 103, 110-111 (1st Cir. 2011) (relators "must show that the defendants knowingly caused the submission of the false or fraudulent claims, the submission of false records or statements to get the false or fraudulent claims paid, or otherwise conspired to defraud the state by getting the false or fraudulent claims paid."). The complaint fails to allege any form of remuneration, and also fails to allege false claims that were submitted as a result of that remuneration. As such, the claim under Count II is dismissed.

c. Count III, Retaliation, 42 U.S.C. § 3730(h)

Abbott argues that Elliott-Lewis' claim of retaliation under the False Claims Act is deficient because "concerns about improper marketing practices or internal company policies . . . fall short of protected activity under the FCA." Def. Mem. in Supp. of Mot. to Dismiss [#15, at 15]. According to Abbott, the FCA retaliation provisions protect activity only if the activity concerns claims for payment. Compl. [#1, ¶ 15-16]. Elliott-Lewis alleges that she was "engaged in protected activity for raising concerns about the marketing and sales tactics used by Abbott, which [s]he believed to be illegal and improper. In retaliation for [her] complaints, Abbott improperly terminated Elliott-Lewis on May 9, 2014." Compl. [#1, ¶ 71].

The False Claims Act provides,

> Any employee, contractor, or agent shall be entitled to all relief necessary to make that employee, contractor, or agent whole, if that employee, contractor, or agent is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee, contractor, agent or associated other in furtherance of an action under this section or other efforts to stop 1 or more violations of this subchapter.

30 U.S.C. § 3730(h)(1) (emphasis added). Generally, the First Circuit has found that "to prevail on an FCA retaliation claim, a plaintiff must show that: he engaged in conduct protected under the FCA; the employer knew that he was engaged in such conduct; and the employer discharged or discriminated against him because of his protected conduct." Maturi v. McLaughlin Research Corp., 413 F.3d 166, 172 (1st Cir. 2005) (internal footnotes/citations omitted); see also Glynn v. EDO Corp., 710 F.3d 209, 214 (4th Cir. 2013) ("The employee's investigation must concern 'false or fraudulent claims' or it is not protected activity under the FCA."). As the First Circuit has noted, in cases such as this, where the alleged retaliation took place prior to the employee's

filing of a qui tam action, "courts have struggled to place tangible limits on what sort of activity qualified for protection under the FCA's anti-retaliation provision." Harrington, 668 F.3d at 33. Although Elliott-Lewis pleaded that she refused "participation in the illegal marketing and promotion of an investigational device," Compl. [#1, ¶ 31], her complaints about illegal activity cannot be considered to be "in furtherance of" a False Claims Act action because they did not concern a claim for payment. While recovery under the False Claims Act is not necessary for a retaliation claim to be successful, the retaliation provisions do require a nexus between the employee's activity and a potential False Claims Action in order to be protected. Mann v. Heckler & Koch Defense, Inc., 630 F.3d 338, 344-45 (4th Cir. 2010).

In United States ex rel. Karvelas, the First Circuit found that "conduct protected by the FCA is limited to activities that 'reasonably could lead' to an FCA action; in other words, investigations, inquiries, testimonies or other activities that concern the employer's knowing submission of false or fraudulent claims for payment to the government." United States ex rel. Karvelas, 360 F.3d at 237. The First Circuit found that while Karvelas demonstrated evidence of a cover-up of regulatory failures, he did not allege the investigation or reporting of false or fraudulent claims submitted to the government. Id. ("'[c]orrecting regulatory problems may be a laudable goal,'" but is not itself protected activity under the FCA) (quoting United States ex rel. Hopper v. Anton, 91 F.3d 1261, 1269 (9th Cir. 1996)); see also, Mann., 630 F.3d at 347 ("[Relator] might have had a reasonable possibility of uncovering evidence [that Defendant] violated federal contracting regulations . . . [but Relator] still would not qualify for FCA protection because the FCA requires fraud, not mere regulatory violations."); Hoyte v. American Nat'l Red Cross, 518 F.3d 61, 67 (D.C. Cir. 2008) ("[A]n employee's investigation of nothing more than his employer's non-compliance with federal or state regulations is not enough to

support a whistleblower claim.") (internal quotation marks omitted). As alleged, the allegations in the complaint are insufficient to state a claim for retaliation under the False Claims Act, and therefore must be dismissed.

V. Conclusion

For the foregoing reasons, the Defendant's Motion to Dismiss [#14] is GRANTED and the complaint is DISMISSED.

IT IS SO ORDERED.

/s/ Indira Talwani
Date: March 28, 2016 United States District Judge